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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,962	02/02/2004	Darin G. Schaeffer	10703/042	9118

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BRINKS HOFER GILSON & LIONE
ONE INDIANA SQUARE, SUITE 1600
INDIANAPOLIS, IN 46204

EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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08/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/769,962	Applicant(s) SCHAEFFER ET AL.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1-3, 5-22, 25-29, 32.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Justine R Yu/
 Supervisory Patent Examiner, Art Unit 3771

/Kristen C. Matter/
 Examiner, Art Unit 3771

Continuation of 11. does NOT place the application in condition for allowance because: In response to applicant's argument that Cox and Stuart does not teach a flange cut-away portion, examiner points to the response to arguments section of the final office action of 6/9/2009. In addition, examiner notes that the flange cut-away portion has been clearly identified as the middle cut out portion of the flange of Stuart. The bearing mechanism (14) of Stuart clearly extends radially inwardly from a lateral side of the cut-away portion of the flange as seen in Figure 1. This piece mates with the groove (34/36) on the collar. Because the radially inwardly extending piece (14) mates with the groove to connect and hold the two together, these two pieces can be considered to be cooperatively sized and shaped. Additionally, in the combination of references the cut-away portion could be seen as a semi-circle covering an entire lateral side of the flange (with a radially inwardly extending piece 14), as the two halves of the flange would be separable as taught by Cox by a snap fit. Examiner continues to point out that the recitation of limitations in the claims are broad and without many structural limitations. For example, in the last paragraph on page 8 of the instant remarks, it is unclear if applicant is suggesting that since the cut-out of Cox is an annular opening that it does not in fact read on a cut-away portion. However, since the middle portion is in fact cut out/removed from the flange, it can be considered a "cut-away" portion in the broadest reasonable interpretation of the claims (i.e., there is no claimed limitation that the cut-out not be annular).

In response to applicant's arguments that there is no motivation to combine Cox with a tapered dilator as taught by Mizus, examiner respectfully maintains that Mizus teaches that tapered loading dilators/obturators are a well known shape for easy insertion into a patient while decreasing risk of injury and increasing comfort. Obturators have the same structure as loading dilators and one of ordinary skill in the art would recognize that the obturator of Mizus would be fully capable of either being used as a loading dilator or that the tapered shape of Mizus would be beneficial to dilators, cannulas, or any other inner tube that is placed in the incision. The combination of the well known shape of Mizus with Cox would therefore yield predictable results that do not patentably distinguish over the prior art of record. Furthermore, a mere change in shape without a change in function does not patentably distinguish over the prior art of record. Examiner also notes that any piecemeal attack on the Mizus reference is irrelevant because the stop member of the instant claims is found in the Cox reference at the top ridge (64) of the tube. Mizus is merely cited to show that the shape of the dilator of Cox could be changed to a tapering tube leading to a tapered distal end as taught by Mizus as an obvious design consideration. Examiner also points again to the response to arguments section of the final action regarding the lack of structural limitations regarding the stop portion and its criticality in relation to the tapered distal end and tapered tube.

In response to applicant's arguments regarding the Varner reference, examiner first points to the response to arguments section of the final action to respond to applicant's continued position that a dilator cannot be reasonably equated to an inner cannula. Furthermore, examiner notes that limitations from the specification are not read into the claims and therefore any distinction made in the specification between a cannula and a dilator are not read into the instant claims. Using any well known locking mechanism (such as that of Varner) on an inner tube/cannula/dilator of Cox would yield predictable results that do not patentably distinguish over the prior art of record. Additionally, as discussed in the final action, the motivation to combine prior art does not need to explicitly address the same problem as the instant invention so long as the structure is the same and motivation to combine the references is found in the references themselves. Again because of the lack of structural limitation, the stop member is merely the bottom surface of the inner cannula/dilator head of Varner, which abuts the top surface of the trach tube to prevent axial movement and is engaged to the securement and complimentary member (see Figure 4).